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U.S. UTILITY PATENT APPLICATION

OF

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FOR

STENT DELIVERY AND DEPLOYMENT METHOD

STENT DELIVERY AND DEPLOYMENT METHOD

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to medical devices, and more specifically to an improved method and apparatus for the delivery and deployment of an implantable stent apparatus for the treatment of narrowing coronary or peripheral vessels in humans.

Description of the Prior Art

Cardiovascular disease, including atherosclerosis, is the leading cause of death in the U.S. The medical community has developed a number of methods and devices for treating coronary heart disease, some of which are specifically designed to treat the complications resulting from atherosclerosis and other forms of coronary arterial narrowing.

An important development for treating atherosclerosis and other forms of coronary narrowing is percutaneous transluminal coronary angioplasty, hereinafter referred to as "angioplasty" or "PTCA". The objective in angioplasty is to enlarge the lumen of the affected coronary artery by radial hydraulic expansion. The procedure is accomplished by inflating a balloon within the narrowed lumen of the coronary artery. Radial expansion of the coronary artery occurs in several different dimensions, and is related to the nature of the plaque. Soft, fatty plaque deposits are flattened by the balloon, while hardened deposits are cracked and split to enlarge the lumen. The wall of the artery itself is also stretched when the balloon

is inflated.

Angioplasty is typically performed as follows: A thin-walled hollow guiding catheter is introduced into the body via a relatively large vessel, such as the femoral artery in the groin area or the brachial artery in the arm. Access to the femoral artery is achieved by introducing a large bore needle directly into the femoral artery, a procedure known as the Seldinger Technique. Once access to the femoral artery is achieved, a short hollow sheath is inserted to maintain a passageway during the procedure. The insertion of the flexible guiding catheter involves the negotiation of an approximately 180 degree turn through the aortic arch to allow the guiding catheter to descend into the aortic cusp where entry may be gained to either the left or the right coronary artery, as desired.

After the guiding catheter is advanced to the ostium of the coronary artery to be treated by angioplasty, a flexible guidewire is inserted into the guiding catheter through a balloon (described infra) and advanced to the area to be treated. The guidewire provides the necessary steerability for lesion passage. The guidewire is advanced across the lesion, or "wires" the lesion, in preparation for the advancement of a balloon catheter composed of polyethylene, polyvinyl chloride, polyolefin, or other suitable substance across the guide wire. The balloon, or dilatation, catheter is placed into position by sliding it along the guide wire. The use of the relatively rigid guide wire is necessary to advance the catheter through the narrowed lumen of

the artery and to direct the balloon, which is typically quite flexible, across the lesion. Radiopaque markers in the balloon segment of the catheter facilitate positioning across the lesion. The balloon catheter is then inflated with contrast material to permit fluoroscopic viewing during treatment. The balloon is alternately inflated and deflated until the lumen of the artery is satisfactorily enlarged.

Unfortunately, while the affected artery can be enlarged, in some instances the vessel restenoses chronically, or closes down acutely, negating the positive effect of the angioplasty procedure. In the past, such restenosis has frequently necessitated repeat PTCA or open heart surgery. While such restenosis does not occur in the majority of cases, it occurs frequently enough that such complications comprise a significant percentage of the overall failures of the PTCA procedure, for example, twenty-five to thirty-five percent of such failures.

To lessen the risk of restenosis, various devices have been proposed for mechanically keeping the affected vessel open after completion of the angioplasty procedure. Such mechanical endoprosthetic devices, which are generally referred to as stents, are typically inserted into the vessel, positioned across the lesion, and then expanded to keep the passageway clear. Effectively, the stent overcomes the natural tendency of the vessel walls of some patients to close back down, thereby maintaining a more normal flow of blood through that vessel than

would be possible if the stent were not in place.

Various types of stents have been proposed, although to date none has proven completely satisfactory. One proposed stent involves a tube of stainless wire braid. During insertion, the tube is positioned along a delivery device, such as a catheter, in extended form, making the tube diameter as small as possible. When the stent is positioned across the lesion, it is expanded, causing the length of the tube to contract and the diameter to expand. Depending on the materials used in construction of the stent, the tube maintains the new shape either through mechanical force or otherwise.

The Palmaz stent (U.S. Patent No. 4,733,665) involves what may be thought of as a stainless steel cylinder having a number of slits in its circumference, resulting in a mesh when expanded. The stainless steel cylinder is delivered to the affected area by means of a balloon catheter, and is then expanded to the proper size by inflating the balloon. Boneau U.S. Patent No. 5,292,331 provides a unitary wire-like stent structure configured to form a plurality of upper and lower axial peaks, and is delivered and expanded in a similar manner.

Significant difficulties have been encountered with known prior art stents, including varying degrees of difficulty in deployment. Currently, some stent delivery systems retain the stent on the delivery catheter by means of either (a) plastically deforming the stent so that it is crimped onto the balloon, or (b) having the stent exhibit a small enough internal diameter to

act as an interference fit with the outside diameter of the balloon catheter. The disadvantage with these methods is that there is a limited amount of securement between the stent and the balloon, which is not always adequate to insure that the stent will properly stay in place while advancing the stent to and through the target lesion. Other known stent delivery systems utilize a removable sheath system on the outside of the stent that is removed once the stent is at the delivery site. This method provides a reliable method for stent delivery, but suffers from the disadvantages of an increased device crossing profile and a decrease in the device's ability to track through the vasculature. This and other complications have resulted in a low level of acceptance for such stents within the medical community, and to date stents have not been accepted as a practical method for treating chronic restenosis.

It is therefore an object of this invention to provide a stent delivery system without an exterior sheath system, while still assuring a reliable stent attachment method.

SUMMARY OF THE INVENTION

The stent delivery and deployment method of this invention provides a frozen-in balloon form to assure stent attachment. This method is especially valuable on the proximal and distal ends of the stent, but may also prove to be effective along the length of the stent within any structural profiles. The stent attachment is achieved by encapsulating the stent and

balloon within a sheath device, and exposing the stent and balloon to an elevated temperature while pressurizing the balloon. This has the effect of forming the balloon around the stent and within the sheath. By cooling the balloon and stent while maintaining pressure in the balloon, the balloon profile will be "frozen" (formed) around the stent.

The stent deployment method of this invention provides multiple (three or more) folded and wrapped "wings" or radial extensions on a balloon delivery device to assure radially symmetrical stent deployment. The preferred embodiment would utilize four folds. Currently, most balloons utilize only two folded and wrapped wings. By utilizing more than two wings, a more symmetrical stent deployment can be achieved. Furthermore, standard PTCA balloon catheters would benefit from more than two folds by assisting in symmetrical expansion of the target lesion.

The method of this invention may be used with a stent apparatus formed from a single piece of wire, formed into sections to define an expandable stent having an inside surface and an outside surface. The resultant stent apparatus can then be formed onto a balloon catheter using the inventive method, delivered to the affected vessel and expanded in place, all as described herein.

The stent, or endovascular support device, of the present invention may preferably be comprised of implantable quality high grade stainless steel, machined specially for intravascular applications. The inventive stent may comprise a

metal circle or ellipsoid formed to create a plurality of axial bends, thereby permitting compression of the stent onto a delivery catheter (if necessary), and subsequent expansion once in place at the affected area.

Some of the intended uses include PTCA type stenting, PTA type stenting, graft support, graft delivery, INR use, GI tract use, drug delivery, and biliari stenting.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side elevation view of a stent and balloon encapsulated within a sheath device;

Fig. 2 is a side elevation view of the encapsulated stent and balloon of Fig. 1 having been exposed to an elevated temperature while pressurizing the balloon, forming the balloon around the stent and within the sheath; and

Fig. 3 is a side elevation view of the stent and balloon of Fig. 2 after cooling the balloon and stent while maintaining pressure in the balloon, so that the balloon profile is "frozen" (formed) around the stent.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Fig. 1 is a side elevation view of a stent and balloon encapsulated within a sheath device. This embodiment is in the form of a short, single wire stent 10 having an expandable, generally cylindrical body portion 12 having an inside surface 14 and an outside surface 16. Balloon 20 is a standard or modified

PTCA balloon. Sheath device 30 is preferably non-expandable, and of a size to accept insertion of the stent and balloon before expansion and forming.

Fig. 2 is a side elevation view of the encapsulated stent 10 and balloon 20 of Fig. 1 having been exposed to an elevated temperature while pressurizing the balloon, forming the balloon around the stent and within the sheath 30.

Fig. 3 is a side elevation view of the stent 10 and balloon 20 of Fig. 2 after cooling the balloon and stent while maintaining pressure in the balloon, and after removal from the sheath, so that the balloon profile is "frozen" (formed) around at least a portion of the stent.

In a preferred embodiment, the inventive stent comprises a single piece of material, bent to form a plurality of upper axial turns and lower axial turns. In the embodiment shown in Fig. 1, a plurality of upper turns are connected to the plurality of lower turns by substantially straight segments. The axial turns can be seen to permit the stent to be compressed or expanded over a wide range while still maintaining a significant mechanical force, such as required to prevent a vessel from restenosing.

The stent is preferably constructed of implantable materials having good mechanical strength, such as implantable quality stainless steel wire. The outside of the stent may be selectively plated with platinum to provide improved visibility during fluoroscopy. The cross-sectional shape of the finished

stent may be circular, ellipsoidal, rectangular, hexagonal, square, or other polygon, although at present it is believed that circular or ellipsoidal may be preferable.

The minimum length of the stent section, or the distance between the upper turns and lower turns, is determined in large measure by the size of the vessel into which the stent will be implanted. The stent will preferably be of sufficient length as to maintain its axial orientation with the vessel without shifting under the hydraulics of blood flow (or other fluid flow in different types of vessels), while also being long enough to extend across at least a significant portion of the affected area. At the same time, the stent should be short enough as to not introduce unnecessarily large amounts of material as might cause undue thrombosis. Typical cardiovascular vessels into which the stent might be implanted range from 1.5 millimeters to five millimeters in diameter, and corresponding stents may range from one millimeter to two centimeters in length. However, in most instances the stent will range in length between 3.5 millimeters and 6 millimeters.

Once the wire size of the stent has been reduced to the desired size, the stent may be applied to a balloon using the method of this invention for delivery to the affected region of a vessel such as a coronary artery. Once the balloon is in place across the lesion, the balloon may be inflated in a conventional manner. In selecting a balloon, it is helpful to ensure that the balloon will provide radially uniform inflation so that the stent

will expand equally along each of the peaks. The inflation of the balloon causes the expansion of the stent. The amount of inflation, and commensurate amount of expansion of the stent, may be varied as dictated by the lesion itself, making the stent of the present invention particularly flexible in the treatment of chronic restenosis.

Because of the inflation of the balloon, the lesion in the vessel is expanded, and causes the arterial wall of the vessel to bulge radially. At the same time, the plaque deposited within the intima of the vessel is displaced and thinned, and the stent is embedded in the plaque or other fibrotic material adhering to the intima of the vessel.

Following inflation of the balloon and expansion of the stent within the vessel, the balloon is deflated and removed. The exterior wall of the vessel returns to its original shape through elastic recoil. The stent, however, remains in its expanded form within the vessel, and prevents further restenosis of the vessel. The stent maintains an open passageway through the vessel, so long as the tendency toward restenosis is not greater than the mechanical strength of the stent. Because of the low mass of the support device of the present invention, thrombosis is less likely to occur. Ideally, the displacement of the plaque deposits and the implantation of the stent will result in a smooth inside diameter of the vessel.

While the primary application for the stent is presently believed to be treatment of cardiovascular disease such

as atherosclerosis or other forms of coronary narrowing, the stent of the present invention may also be used for treatment of narrowed vessels in the kidney, leg, carotid, or elsewhere in the body. In such other vessels, the size of the stent may need to be adjusted to compensate for the differing sizes of the vessel to be treated.

While this invention has been described in connection with preferred embodiments thereof, it is obvious that modifications and changes therein may be made by those skilled in the art to which it pertains without departing from the spirit and scope of the invention. Accordingly, the scope of this invention is to be limited only by the appended claims.